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Bard Peripheral Vascular, Inc.*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**THE PARTIES' SUBMISSION RE:
DISCOVERY ABOUT THE SIMON
NITINOL FILTER**

DISCOVERY REGARDING SIMON NITINOL FILTER

Pursuant to Case Management Order No. 8, Paragraph VII [Doc. 519], the parties submit their report regarding discovery about the Simon Nitinol Filter. Plaintiffs requested from Bard six categories of documents relating to the Simon Nitinol Filter (SNF):

- design materials, including design history file
- testing of the SNF, including but not limited to lab testing, bench testing, clinical testing, and animal testing
- regulatory communications, including submissions and communications with the FDA or any regulatory agency

- sales and marketing, advertising, and promotional materials
- comparative information involving the SNF, including all documents in any way discussing analyzing or relating to the performance of other IVC filters
- internal communications regarding the SNF on any of the foregoing subjects and efficacy, performance, and safety of the SNF

The parties have met and conferred regarding Plaintiffs' requests, and as directed by the Court, outline their respective positions as to each category of requested information as follows:

1. Relevance of SNF discovery generally

<u>Plaintiffs' Position</u>	<u>Defendants' Position</u>
<p>Defendants characterize the SNF as having "marginal relevance" to this suit. However, for every filter in this MDL, Defendants obtained FDA clearance to market and sell those devices based on the contention that the newer retrievable filters are "substantially equivalent" to the SNF.</p> <p>While Defendants suggest that the SNF is the predicate device only for the Recovery filter, each of their successive filters identifies the immediately preceding device as its predicate and, thus, all trace back to the SNF. They cannot avoid their reliance on the SNF by a shell game of subsequent filters where they all trace back to the SNF.</p> <p>It is also misleading to suggest that comparisons of this original predicate device to the entire "line of Recovery filters" (Bard's reference) are of little or no relevance. The lack of substantial equivalence to the SNF by any subsequent device is relevant to whether Bard's use of later devices as predicates violated FDA regulations, as well as common law duties to manufacture, design, and sell the best possible device per best available standards of safety and effectiveness. Moreover, Bard continues to sell the SNF; many of their internal comparisons of safety and efficacy are to the SNF; and the SNF is a clearly safer alternative design by their own admission. This means that those filters</p>	<p>In an effort to justify expansive discovery regarding the Simon Nitinol filter, the Plaintiffs misconstrue the regulatory term of art "substantial equivalence." Under FDA parlance, two products can be "substantially equivalent" if they have the same intended use even if very different technological characteristics, so long as the newer product does not raise new questions of safety and effectiveness, and data demonstrates that the newer product has comparable safety and effectiveness as the older device. <i>See</i> 21 U.S.C. § 360c(i)(1)(A). In fact, from the first Bard submission to the FDA regarding the Recovery Filter (which, contrary to the plaintiffs' claim is the <u>only</u> Bard filter that used the Simon Nitinol as a "predicate device") in 2002, it has been abundantly clear that the devices are radically different in fundamental ways.</p> <p>Most telling, the Simon Nitinol filter is a permanent filter which, once implanted, is intended to remain in place for the patient's lifetime. By contrast, the Recovery filter (and all subsequent generations of Bard filters) are intended to be retrievable at the option of the physician and the patient. In view of that distinction in the use of the devices, there are necessarily fundamental design differences between the Simon Nitinol filter and the subsequent retrievable filters, and the FDA has been fully apprised of those distinctions in every pertinent regulatory submission. Given those circumstances, the Simon Nitinol filter has</p>

both perform the same function and have substantially the same safety profile as the SNF. Plaintiffs intend to prove that claim is false.

Defendants have also represented to doctors and the public that their subsequent filters were better than the SNF. Plaintiffs should be permitted to take discovery regarding those representations as well as regarding the representations Defendants made regarding the permanent SNF while they were marketing their “optional” retrievable devices. Bard admits in prior corporate depositions that “first and foremost” their retrievable devices are permanent devices. In fact, the Recovery filter was originally cleared to market as a permanent device only and no design changes were made before receiving its optional retrievability clearance. Then, for the first 2-1/2 years, the Bard G2 filter was on the market it was only a permanent device. Comparisons of the products are definitely relevant. As Bard’s Vice President of Clinical Affairs stated at the time, “the G2 is a permanent filter; we also have one (the SNF) that has virtually no complaints associated with it. Why shouldn’t doctors be using that one rather than the G2? Can you also send me the total complaints rate and MDR complaint rate for SNF?”

Each requested category is designed to obtain information to refute Defendants’ contentions of substantial equivalence, as well as their misrepresentations in official corporate messaging and marketing that the IVC Filters that are the subject of this MDL are equivalent or superior to the SNF in their safety profiles and effectiveness. These misrepresentations and comparisons are directly relevant to Plaintiffs’ allegations of multiple violations of the Code of Federal Regulations, as well as common law negligence, fraud, deceit, and intentional misconduct.

As additional analysis of MAUDE data and new discovery undertaken with respect to the FDA warning letter has occurred, and this litigation now embraces many later generation devices that have not been the

marginal relevance in this litigation (which involves only the retrievable filters), and the mere identification of that earlier device as a predicate device for the regulatory filings does not somehow conflate those very different devices (in function and design). Any “head to head” comparison between the permanent Simon Nitinol filter and the retrievable devices is tantamount to the proverbial “apples and oranges” comparison.

Despite the marginal relevance of the Simon Nitinol filter, Bard has already produced during the course of this litigation most – if not all – of the core materials regarding the device. Moreover, PLC members and their experts have used that core material throughout this litigation, including during the *Phillips* trial, to claim that the SNF is a significantly safer design.

Moreover, the Plaintiffs’ insistence that a great deal of additional information has yet to be produced overlooks the history of the filter. The filter was developed almost 30 years ago by another company, NMT Medical, and first received FDA clearance in 1990. Although Bard sold the product during the 1990’s through a distribution agreement with NMT, Bard did not acquire the rights to the Simon Nitinol filter until 2001. Since purchasing the device then, Bard has not modified the device. (The last 510(k) submission modifying the device was submitted by NMT in 1997.)

Bard has never conducted testing regarding the device, other than some comparative tests with the Recovery and G2 filters (which have already been produced during this litigation). Nor has Bard assembled a distinct team to handle the Simon Nitinol filter; instead, that device has always been the responsibility of the same team handling the retrievable filters, comprised of the same individuals whose files and ESI have already been collected and searched.

Under these circumstances, Bard submits that the comprehensive production that has already occurred should be more than ample in view of the marginal relevance of the earlier device.

subject of extensive prior litigation, the importance of fully understanding the SNF issues has taken on increased importance.

Discovery of SNF information is also relevant to the risk-benefit analysis for the product liability claims in this MDL, and Plaintiffs intend to demonstrate that the SNF presents a significantly safer design than the IVC filters at issue in this MDL. While Defendants attempt to distinguish the SNF from their other filters because it is a permanent filter, that is a distinction without a difference, even aside from the fact that both the Recovery and G2 filters were originally cleared and sold as permanent devices only. First, Defendants themselves used the SNF as the predicate device for the Recovery filter. Moreover, as Defendants acknowledge, Plaintiffs have in the past and intend in this MDL to argue the SNF as a significantly safer design.

Finally, Defendants suggest that the SNF was designed by another company as if that somehow makes it less relevant. Regardless, Defendants acquired and sold the SNF filter for years and acquired the filter (and presumably all rights and assets related to it in 2001). Presumably Bard acquired information both during the time it sold the device and based on its acquisition.

2. Design materials, including design history file

Plaintiffs' Position

As to design information for the SNF, Defendants rely entirely on their production of some SNF related documents in prior matters as being sufficient production in this MDL. However, Defendants have never undertaken to perform an actual diligent search for SNF documents, and particularly to locate and produce SNF design documents and ESI. They have never identified potential custodians and locations within their information systems of SNF documents and ESI.

Rather, in productions in prior suits, Defendants searched ESI (collected from custodians, drives, and locations identified for other filters) using the keywords "SNF"

Defendants' Position

The Defendants object to this request to the extent that it seeks "all" design materials which, construed literally, could include many different types of documents. Given the marginal relevance of the Simon Nitinol Filter to this litigation, the Defendants believe such a sweeping request is unduly burdensome. Additionally, because all design activity regarding the device occurred long before Bard acquired the rights to the Simon Nitinol Filter, it would be particularly burdensome for the Defendants to try to locate any additional documents NMT may have created during their design activities, beyond the core documents that have already been produced. Further, the Plaintiffs'

and “Simon Nitinol.” They have never conducted a search or collection specific to the SNF.

Simply, it is not sufficient for Defendants to rely on keyword searches of ESI collected for other purposes. Plaintiffs request that Defendants perform a diligent search to locate and produce the relevant documents and ESI for the SNF, including those that relate to its design materials.

suggestion that there may be “potential custodians and locations” regarding the Simon Nitinol Filter that have never been collected or searched reflects a fundamental misunderstanding of the history of the device (as described above).

Nevertheless, the Defendants have previously produced the Design History File and Fact Books regarding the Simon Nitinol Filter (Bates Nos. BPV-17-01-00081780 through BPV-17-01-00082065, BPV-17-01-00109315 through BPV-17-01-00110330, BPV-17-01-00111378 through BPV-00111387, and BPV-17-01-00111444 through BPV-17-01-00111955), which contain extensive information (including specifications, testing, etc.) about the device.

3. Testing of the SNF, including but not limited to lab testing, bench testing, clinical testing, and animal testing

Plaintiffs’ Position

As in their marketing material and official corporate approved messaging, Defendants have represented the equivalence or superiority of the devices that are the subject of this litigation in their preclinical tests, including lab, bench, clinical and animal testing.

Again, Defendants have never undertaken a diligent search to find the actual tests and test information related to the SNF. While some of the documents and information Defendants have produced include some information relating to SNF testing, they have never undertaken a specific effort to locate and produce this information. They contend the materials they have produced “contain testing” and that the original FDA submission includes “testing information.” However, they do not contend they have searched for, let alone produced, all the tests they have for the SNF.

Plaintiffs simply request that Defendants respond to this request and demonstrate that they have taken reasonable steps to locate and produce responsive documents. To date, they have not done so.

Defendants’ Position

The Design History File and the Fact Books regarding the Simon Nitinol Filter contain testing performed for the development and introduction of the device (Bates Nos. BPV-17-01-00081780 through BPV-17-01-00082065, BPV-17-01-00109315 through BPV-17-01-00110330, BPV-17-01-00111378 through BPV-00111387, and BPV-17-01-00111444 through BPV-17-01-00111955).

Additionally, the original 510(k) submission for the SNF includes testing information about the device (Bates Nos. BPV-17-01-00112063 through BPV-17-01-00112373. All of that testing was performed by NMT as a part of the development of the device. As previously noted, Bard did not conduct testing itself regarding the Simon Nitinol Filter, other than a small number of tests comparing the attributes of that filter with those of the Recovery Filter and the G2 (and the documentation of that testing has previously been produced).

Given the marginal relevance of the device to this litigation, the Defendants object to

	the extent the request may also be intended to encompass any and all additional testing that may have been performed by NMT years ago.
4. <u>Regulatory communications, including submissions and communications with the FDA or any regulatory agency</u>	
<u>Plaintiffs' Position</u>	<u>Defendants' Position</u>
<p>On this subject, Defendants have agreed to conduct a diligent search to determine what additional documents exist. Plaintiffs agree that is appropriate.</p>	<p>The Defendants have already produced the 510(k) application that resulted in the original clearance of the Simon Nitinol Filter, as well as subsequent 510(k) applications involving minor modifications to the device (Bates nos. BPV-17-01-00109425 through BPV-17-01-00109533, BPV-17-01-00109956 through BPV-17-01-00110134, and BPV-17-01-00111956 through BPV-17-01-00112934).</p> <p>The Defendants will conduct a diligent search and produce any additional regulatory communications that can be located. The Defendants note, however, that the last 510(k) application regarding the Simon Nitinol Filter was filed by NMT in 1997, so there will most likely not be much more in the way of documentation other than the extensive materials already produced.</p>
5. <u>Sales and marketing, advertising, and promotional materials</u>	
<u>Plaintiffs' Position</u>	<u>Defendants' Position</u>
<p>Defendants have not made an effort to locate the sales, marketing, advertising, and promotional materials for the SNF. Thus, they have failed to demonstrate that it would be unduly burdensome to produce those materials.</p> <p>As explained in more detail in Section 1, this request is designed to obtain information regarding Defendants' representations regarding the safety and effectiveness of the SNF to refute Defendants' contentions of substantial equivalence, as well as Defendants' misrepresentations in corporate messaging and marketing that the IVC Filters that are the subject of this MDL are equivalent or superior to the SNF in their safety profiles</p>	<p>Plaintiffs claim that these SNF sales and marketing materials are somehow relevant to prove "Defendants' misrepresentations in corporate messaging and marketing" regarding the Recovery® through Denali® Filters. But Plaintiffs fail to articulate how the contents of an SNF sales or marketing material tends to prove or disprove a claim in a sales or marketing material related to some other device.</p> <p>Given the marginal relevance of the Simon Nitinol Filter to the issues in this litigation, the Defendants object to this request because of the undue burden it would impose. The Simon Nitinol Filter has been sold for 25 years, and any effort to collect and produce all "marketing, advertising,</p>

1	and effectiveness.	and promotional materials" over such a lengthy period would be an enormous undertaking. The Defendants would propose as an alternative that they produce representative marketing materials regarding the device.
2	Defendants should be required to conduct a diligent search to locate responsive materials and demonstrate the actual burden of collecting and producing them prior to any limitation being placed on Plaintiffs' right to discover these materials.	
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5	6. <u>Comparative information involving the SNF, including all documents in any way discussing, analyzing, or relating to the performance of other IVC filters</u>	
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7	<u>Plaintiffs' Position</u>	<u>Defendants' Position</u>
8	The primary relevance of the SNF is that it is (a) a significantly safer design than literally all of Defendants' retrievable filters that are the subject of this MDL and (b) Defendants relied on the SNF as the predicate device for all of those filters to obtain FDA clearance to market and sell them. Indeed, prior discovery has revealed that Defendants performed comparisons as to performance and safety as between their other filters and the SNF. Such comparisons are relevant to virtually every claim in this MDL.	In view of the marginal relevance of the Simon Nitinol Filter to the issues in this litigation, the Defendants object to this request. The request is extremely broad, in that it would require the Defendants to search multiple sources of information throughout the companies. Additionally, taken literally, the request for "all documents in any way discussing, analyzing, or relating to the performance of other IVC filters" would require the production of virtually every shred of paper (or byte of data) referencing any IVC filter.
9	Defendants contend the request is "broad" but it is, in fact, quite narrow – it asks for all comparative information. What Defendants really argue is that the request is somehow unduly burdensome. But, again, they have neither done a search to determine where such information exists and what they would have to review or made any demonstration it would be unduly burdensome. The contention that they would have to produce "every shred of paper" is a red herring – Plaintiffs are asking only for comparative documents and information.	The Defendants have already produced hundreds of pages of comparative analyses performed over the years, comparing reported complication rates of the Simon Nitinol Filter with both other Bard filters and competitors' filters. Just a few examples of the documents evidencing those comparisons can be found at Bates Nos. BPV-17-01-00023746 through BPV-17-01-00023752, BPV-17-01-00097313 through BPV-17-01-00097341, BPV-17-01-00097459 through BPV-17-01-00097490, BPV-17-01-00097492 through BPV-17-01-00097525, BPV-17-01-00097529 through BPV-17-01-00097588, BPV-17-01-00097589 through BPV-17-01-00097622, BPVE-01-01697972, and BPVEFILTER-01-00136074. The Defendants also note that the request seeks some materials that are privileged.
10	Defendants again contend they have produced similar information or some of what would be responsive to this request. But, again, those were productions in response to requests for other filters. They have never conducted a specific search for these materials.	
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7. Internal communications regarding the SNF on any of the foregoing subjects and efficacy, performance, and safety of the SNF

<u>Plaintiffs' Position</u>	<u>Defendants' Position</u>
<p>Again, Defendants contend that a category of documents is unduly burdensome without demonstrating that they have taken any effort whatsoever to determine where responsive information would be and what would be required to produce them. Contrary to Defendants' implication, this request does not seek every communication ever regarding the SNF. Rather, it is limited to the subject matter of the prior requests and the efficacy, performance, and safety of the device.</p> <p>Regardless of the amount of time the device was manufactured and sold, there are presumably a limited number of locations that such communications about the SNF are likely to exist. Indeed, those are the same types of locations that exist for the other devices for which Defendants have produced documents.</p> <p>And, Defendants' reliance on their prior productions as being sufficient in this litigation is misplaced. The keyword searches for "SNF" and "Simon Nitinol" were run against ESI collected from locations and custodians specific to other filters. Moreover, Defendants have not demonstrated that their production review process included SNF documents as "responsive" for purposes of production – the fact that some relevant documents were captured by the electronic searches does not mean that the following human review did not remove them as irrelevant in the suits in which the productions were made.</p> <p>Defendants should have to conduct a diligent search for responsive documents and produce additional documents that can be located.</p>	<p>The Defendants object to this request in its entirety because of its sweeping breadth and the enormous burden (both in terms of cost and in terms of labor) it would impose on the companies. This request seeks virtually any and all communications within the company concerning the Simon Nitinol Filter over the 25-year period the device has been marketed. The request would require the Defendants to search the electronically-stored information of scores (likely hundreds) of employees of the companies over those 2 ½ decades. In that regard, Bard notes that the Plaintiffs do not seek the search of the ESI for specific custodians, do not seek the use of specific search terms, and do not limit their request to specific entities or a specific time period.</p> <p>Taken literally, the Plaintiffs' request seeks the processing of an enormous amount of ESI, on a quest that is tantamount to seeking the proverbial "needle in a haystack." The Defendants respectfully submit that such a sweeping request would be overreaching in any circumstances, and is especially so in litigation where the Simon Nitinol Filter has only marginal relevance.</p> <p>The Defendants further note that the terms "Simon Nitinol" and the acronym "SNF" are search terms that have been utilized in previous productions of electronically stored information. And, contrary to the Plaintiffs' misplaced suggestions to the contrary, the same Bard employees involved with the retrievable filters have also had responsibility for the Simon Nitinol Filter from the moment Bard first obtained the rights to the filter in 2001. Finally, the Defendants note that the request as drafted is broad enough to include privileged documents.</p>

DATED this 21st day of March 2016.

GALLAGHER & KENNEDY, P.A.

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of March, 2016, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Mary E. Torrez

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